

70. (New) The method of claim 69 wherein the amount of fluid administered to the eye is 1 to 2 microliters.

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71. (New) A method for moisturizing the eye comprising administering to the surface of the eye an aqueous fluid consisting essentially of water in the form of a mist of droplets having an average size less than 20 microns in diameter, wherein the amount of fluid that is administered to the eye is between 1 and less than 3 microliters, and permitting the fluid to moisturize the aqueous layer of the tear film.

72. (New) The method of claim 71 wherein the average size of the droplets is between 10 and less than 20 microns.

73. (New) The method of claim 71 wherein the amount of fluid that is administered is less than about 2 microliters.

74. (New) The method of claim 73 wherein the amount of fluid that is administered is 1 to 2 microliters. - -

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#### REMARKS

Applicant submits this Amendment in response to the Office Action of May 17, 2001, which was a final rejection of all pending claims. Applicants submit with the Amendment a

Request for Continued Prosecution of this application according to 37 C.F.R. §1.114 and the required fees according to 37 C.F.R. §1.17(e).

All pending claims have been canceled without prejudice and have been replaced by the present claims 44 to 74. New claims 44 to 74 contain 5 sets of claims each beginning with an independent claim: claims 44 to 50, claims 51 to 57, claims 58 to 64, claims 65 to 70, and claims 72 to 74.

The newly added claims find support in the specification and in the previous claims as follows. Independent claims 44, 51, 58, 65, and 71 each contain the features of canceled claim 1. New independent claim 65 is identical to previous claim 1. Additional features of these independent claims are found in the specification on page 6, lines 9-12, page 7, lines 25-30, and page 6, lines 19-32. New dependent claim 45 is identical to previous claim 3. Newly added claims dependent from these independent claims have support in the specification on these same pages.

## REJECTIONS OF PENDING CLAIMS

### I. Rejection under 35 U.S.C. §102 (b)

The Examiner has rejected pending claims 1-12, 15-18, 24-25, 28-29, and 42-43 as being anticipated by Embleton et al (WO 97/23177) under 35 U.S.C. §102(b). Applicant traverses the rejection of the claims on this ground.

Embleton discloses the administration to the eye of an ophthalmic treatment liquid in the form of a jet or stream of droplets. See page 3, lines 1-4. Embleton discloses that the sizes of droplets that are suitable for the invention are at least 20 microns. See page 3, lines 21-23.

Embleton discloses a minimum range of volume of treatment fluid to be between 3 to 8 microliters. See page 3, last line. Embleton further discloses that the ophthalmic treatment liquids that may be used with the invention includes:

- 6) Artificial tear/dry eye therapies, comfort drops, irrigation fluids, etc., e.g. physiological saline, water, or oils; all optionally containing polymeric compounds such as acetylcysteine, hydroxyethylcellulose, hydroxymellose, hyaluronic acid, polyvinyl alcohol, polyacrylic acid derivatives, etc.

The present invention distinguishes over Embleton in several ways.

- (1) Embleton does not disclose treatment with an aqueous fluid that consists essentially of water, as was called for in all previously pending claims and is presently called for in new claims 45, 57, and 64-74.

Attached hereto is Exhibit 1, Physicians' Desk Reference (PDR), 48 ed., pages 471, 472, and 2528 (1994). Page 471 discloses Eye-Stream®, a sterile ophthalmic eye irrigating solution. Page 472 discloses Tears Naturale® II and Tears Naturale Free®, an artificial tear formulations. Page 2528 discloses Collyrium for Fresh Eyes, an eye wash, and Collyrium Fresh™, sterile eye drops for relieving discomfort.

Each of the ophthalmic preparations disclosed above is an aqueous formulation that contains ingredients other than water, which other ingredients are essential to the formulations' beneficial activities. One skilled in the art would understand Embleton's disclosure of "artificial tear/dry eye therapies, comfort drops, and irrigation fluids, e.g. physiological saline, water, or oils" to mean artificial tear/dry eye therapies, comfort drops, and irrigation fluids that are based

on physiological saline, water, or oils. One skilled in the art understands that these products, as presently known, contain ingredients other than water, which other components necessary in order for these products to provide their benefits to the user.

For example, artificial tears formulations contain one or more polymers. See page 472 of the PDR, Exhibit 1. The polymer may be, as disclosed in Embleton, hydroxymethyl cellulose. One skilled in the art knows that the polymer is an essential component of artificial tears. As another example, the irrigating solution and eye wash on pages 471 and 2528 of the PDR, Exhibit 1 contain various tonicity agents and buffering agents. Moreover, an irrigating agent, by its very nature, is not applicable to the present invention because, in order to irrigate, it must be administered in sufficient volume to wash away foreign material that is in contact with the eye. As a third example, on page 2528, the eye drops for relief of discomfort contain active ingredients other than water such as tetrahydrozoline and glycerin.

Applicant submits that Embleton does not disclose an artificial tear/dry eye formulation, or a comfort drop, or an irrigation solution that consists essentially of water and which is used as claimed in the present application. Rather, Embleton discloses such formulations, drops, or solutions that are based on water, with the understanding that such formulations, drops, or solutions would by necessity contain additional necessary components. It is clear that this is what the Embleton reference discloses. If Embleton had intended to disclose water, the disclosure would have simply stated that water is suitable for the invention, rather than the listed formulations, drops, or solutions.

Accordingly, Applicant submits that the rejection of the pending claims for anticipation over the disclosure of Embleton is overcome and requests that the Examiner withdraw the rejection of the claims on this ground.

2) The new claims, and several of the previously pending claims, contain additional limitations that distinguish over Embleton.

a) The present invention, as claimed in claims 44 to 50, is a method for moisturizing the eye that comprises administering a mist to the eye. Enclosed herein as Exhibit 2 is page 1231 of the Random House Dictionary of the English Language (1987). The term "mist" is defined as:

1. a cloudlike aggregation of minute globules of water suspended in the atmosphere at or near the earth's surface, reducing visibility to a lesser degree than fog. 2. a cloud of particles resembling this: *She sprayed a mist of perfume onto her handkerchief.* . . (emphasis in the original)

Embleton does not disclose a mist. Rather, Embleton discloses a jet or stream of droplets.

b) The present invention, as claimed in claims 51 to 57, is a method for moisturizing the eye that comprises administering between 1 and less than 3 microliters of fluid to the eye. Embleton does not disclose that such small amounts of fluid may be used. Rather, Embleton discloses a range of 3 to 8 microliters.

c) The present invention, as claimed in claims 58 to 64, is a method for moisturizing the eye that comprises administering a fluid to the eye in the form of a multiplicity of droplets having an average diameter of less than 20 microns. Embleton does not disclose such small droplets. Rather, Embleton discloses that droplets of at least 20 microns in diameter.

d) Further, several claims of the present application (e.g. claims 46-50, 54-56, 60-63, and 71-74) call for a combination of these three features not disclosed or suggested by Embleton.

Accordingly, Applicants submit that each of the present claims contains at least one feature not disclosed or suggested by Embleton and that, therefore, the present claims are not anticipated by Embleton under 35 U.S.C. §102(a).

## II. Rejection under 35 U.S.C. §103(a)

The Examiner has rejected claims 1 to 43 under 35 U.S.C. §103(a) as being obvious in view of the combined disclosure of Embleton and Rocca et al (WO 96/00050) in view of Varma (U.S. Pat. No. 5,032,392). Applicant traverses the rejection of the claims on this ground.

As discussed above, Embleton neither discloses nor suggests the present invention as claimed. The secondary references, Rocco and Varma, do not fill in the gaps in the disclosure of Embleton that would render the present claims obvious. Rocco, like Embleton, discloses a jet of multiple droplets. Rocco does not disclose a mist. Rocco discloses a treatment volume of 5 microliters, (page 8, line 19) in contrast to the presently claimed less than 3 microliters. Rocco further discloses a droplet size of between 20 to 200 microns, in contrast to the presently claimed less than 20 microns.

Varma is cited for its disclosure of pH and is not pertinent to the present claims.

Accordingly, because the combined disclosure of Embleton, Rocco, and Varma does not suggest the present invention, Applicant submits that the present claims are patentable over these references.

## CONCLUSION

Applicant submits that the claims, as amended herein, are in condition for allowance and requests an early notice to that effect.

Respectfully submitted,

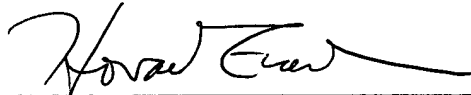


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## CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Box AF, Assistant Commissioner for Patents, Washington, D.C. 20231, on July 9, 2001.

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